

## **NIH POLICY MANUAL**

### **1340-1 - PERMITS FOR IMPORT OR EXPORT OF BIOLOGICAL MATERIAL**

**Issuing Office: ORS/DS 496-2346**

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1. **Explanation of Material Transmitted:** This chapter is being revised to remove sections pertaining to importation and exportation procedures of rodents and rodent products.
2. **Filing Instructions:**  
  
    **Remove:** NIH Manual 1340-1, dated 5/25/90 in entirety.  
    **Insert:** NIH Manual Chapter 1340-1 dated 11/15/96
3. **Distribution:** NIH Manual Mailing Keys F401, and F402

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#### **A. Purpose:**

This chapter describes the NIH policy and procedures concerning the requirements for permits for the importation or shipment of etiologic agents, their vectors, animals and plants, and for the exportation of biological materials. Failure to comply with import and export requirements may result in shipment release delays or shipment confiscation and destruction by the quarantine officer at the port of entry.

#### **B. Background and References:**

1. Legislative Sources:
  - a. Pursuant to Section 215 of the Public Health Service Act, as amended (42 U.S.C. 216) and Sections 71.54 and 72.3 of Title 42 of the Code of Federal Regulations (CFR), the pertinent Public Health Service

quarantine regulations state:

"A person may not import into the United States nor distribute after importation, any etiologic agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director" (i.e., Director, Centers for Disease Control, Public Health Service, Department of Health and Human Services, or his/her authorized representative).

b. U.S. Department of Agriculture (USDA) regulations (Section 122.2 of Title 9, CFR) require:

"No organisms or vectors shall be imported into the United States or from one state or Territory or the District of Columbia to another state or Territory or the District of Columbia without a permit issued by the Secretary and in compliance with the terms thereof."

Note the USDA will not permit the importation of cell cultures, monoclonal antibodies, ascites fluid or bovine serum from countries where rinderpest and foot-and-mouth disease are present unless the imported materials are determined to be virus-free.

c. Similar Department of Agriculture regulations are concerned with plant disease agents and vectors (Title 7 CFR Part 330). These regulations seldom affect the work of biomedical investigators. However, certain human disease vectors or potential vectors are also plant disease vectors and come under the control of these regulations.

d. The United States Fish and Wildlife Service (USFWS), U.S. Department of Interior is responsible for regulations involving the prevention and control of wildlife diseases, and for the importation of wildlife and eggs thereof (50 CFR Parts 13 and 14). If biomedical investigators wish to use these materials in research, the requirements of these regulations must be met. The importation of certain animals and birds is prohibited.

e. The Department of Commerce administers the Export Control Act of 1949 (as amended) and regulations involving exports of "commodities and technical data" to all countries except Canada; this includes the control of biological materials.

f. Imported and exported biological materials and etiologic agents are subject to packaging and shipping requirements of various federal and international regulations. Proper packaging is the primary consideration and of utmost importance in the safe transportation of hazardous materials. The PHS regulations (42 CFR Part 72, Interstate Shipment of

Etiological Agents)dictate the proper packaging requirements necessary for most biological materials.

g. Guidance for the classification and containment standards for Biosafety Level (BL) agents 1-4 is provided in the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories.

2. Delegations:

a. Responsibilities of the Secretary, HHS, identified in 1. a. above, have been delegated to the Foreign Quarantine Program, Office of Health and Safety, Centers for Disease Control, Atlanta, Georgia. That office has authorized NIH to issue permits for the importation of etiologic agents and vectors of human disease into NIH laboratories. It is a condition of this authorization that NIH maintain a record of each permit issued and document the transfer of all PHS-permitted material.

b. NIH has established a Quarantine Permit Service Office (QPSO), Division of Safety (DS), Office of Research Services (ORS), Building 13, Room 3K04 (496-3353) for the issuance of the PHS and USFWS permits, Export License and the maintenance of the required records. Although the QPSO does not issue USDA permits, it will provide the application form (VS 16-3) and information for obtaining USDA permits to import USDA-controlled materials.

**C. Policy:**

NIH will conform to all applicable laws and regulations for the importation and shipment of etiologic agents and vectors.

No person at NIH shall make arrangements to receive or ship an etiologic agent, vector, animal, or plant before ascertaining the necessity for a permit and obtaining such a document when required.

No person at NIH shall transfer PHS-permitted materials to another laboratory or facility within NIH or to other Federal or private facilities without prior authorization by the appropriate agency or office (CDC or QPSO).

**D. Responsibilities:**

The ORS, DS is responsible for providing information and guidance to NIH components on the requirements for Import or Export of Biological Materials.

It is a responsibility of each ICD Director and any other supervisory officer to assure compliance by all staff members with the requirements of regulations involving the importation and exportation of etiologic agents, vectors, animals, and plants.

The QPSO issues PHS, USFWS, and export permits to the NIH community, maintains

records, and submits reports to the regulatory agencies. The QPSO requires that a request for a permit to import an etiologic agent requiring BL3 or BL4 containment be submitted with written concurrence of the ICD Scientific Director. The requirement for obtaining permits from more than one agency will be determined by the QPSO. The QPSO will also provide advice and assistance with obtaining USDA permits.

While the responsibilities of the agencies are limited to each specific mission (i.e. PHS for human pathogens, and USDA for animal or plant pathogens) many etiologic agents are pathogens of animals and of humans and thus both agencies may be involved in the permitting process. A close liaison is maintained between the PHS and USDA offices responsible for control of the importation and shipment of etiologic agents and vectors.

#### **E. Procedures:**

##### **1. Imports:**

a. To ascertain the need for a permit to receive or ship an etiologic agent, vector, animal or plant, telephone the QPSO at 496-3353 at least six calendar weeks before the date of shipment in order to allow adequate time for processing the permit request.

b. An individual wishing to import or to make shipment to another NIH/PHS laboratory, may obtain a PHS or USFWS permit by submitting the application, Form CDC 0.753, "Application for Permit to Import or Transport Agents or Vectors of Human Disease," or Form USFWS 3-177, "Declaration for Importation or Exportation of Fish or Wildlife" to the QPSO. Forms can be obtained from the QPSO, Building 13, Room 3K04 (See Appendices 1 and 2).

Individuals wishing to apply for a USDA Animal and Plant Health Inspection Service (APHIS) permit must submit their permit application directly to the USDA. An information guide, "APHIS Facts" and application (VS 16-3) are available from the QPSO (See Appendix 3). Both a USDA and a PHS permit may be required for the importation of some biological materials. The QPSO can advise individuals on their permit needs; the individual is responsible for obtaining the required permit(s).

c. A NIH investigator may transfer imported biologic materials to another qualified investigator within the NIH providing he/she first submits Form CDC 0.753, "Application for Permit to Import or Transport Agents or Vectors of Human Disease" to the QPSO, Building 13, Room 3K04 and subsequently receives authorization from the QPSO.

d. Transfer of imported biological materials from the NIH to other research activities under the control of PHS or in the private sector

within the United States can be accomplished only by the authority of CDC. Investigators desiring to receive such transfers must submit Form CDC 0.753, "Application for Permit to Import or Transport Agents or Vectors of Human Disease," directly to the CDC, Office of Health and Safety, 1600 Clifton Road, Atlanta, Georgia, 30333, (404)-639-3883).

No Person at NIH shall distribute a permitted etiologic agent or vector of human disease unless the intended recipient provides a copy of the appropriate permit authorizing their receipt of the material.

2. Exports: Export License. In general, biological materials may be exported to most countries of the world under the provisions of a published "General License G-DEST" authorization of the Commerce Department's Office of Export Control. A specific "Validated Export License" must be obtained, through the QPSO by submitting Form NIH-2388, "Declaration for Exportation of Biologic Materials", to export biological agents such as viruses, bacteria, fungi, and parasites or products thereof (See Appendix 4). Copies of Form NIH-2388 are available from the QPSO. Whether or not validated license will be required for a particular shipment will depend upon the identity of the biological agent, the proposed country of destination, and the value of the shipment. This determination is made by the QPSO.

The shipper must determine whether an import permit is required or if import restrictions exist for the shipment of materials into the recipient's country. If an import permit is required, the permit number or a copy of the import permit must be included with the request for exportation of biologic materials.

3. Interstate Shipments: In general, indigenous etiologic agents and vectors are not subject to control by Federal or other agencies for U.S. interstate shipments but there are some exceptions (e.g., plant pests, the establishment of a colony of *Aedes aegypti* mosquitoes, and the transport of blue tongue of sheep). Contact the QPSO for guidance before transporting etiologic agents which may be subject to interstate shipment restrictions.
4. Packaging Requirements: Diagnostic specimens and biological products are subject to minimum packaging requirements described in 42 CFR, Part 72.2, Interstate Shipment of Etiologic Materials, which specifies that such material must be packaged "to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation."

Materials known or presumed to contain a viable microorganism or its toxin which causes or may cause human disease are subject to additional packaging and shipping requirements. Section 72.3 of the PHS Interstate Shipment of Etiologic Agents regulations describes packaging, labeling, and shipping requirements based on the volumes of the primary container (i.e. volumes less than 50 ml and volumes greater than 50 ml). In each case, the material is placed in a securely closed, watertight primary container which is surrounded by an

absorbent packaging material. The primary container is then sealed in a durable, watertight secondary container (several primary containers may be enclosed within a secondary container). Each set of primary and secondary containers are enclosed in an outer shipping container (See Figure 2 of Appendix 5).

A label indicating the names and addresses of the sender and the addressee should be affixed to the outer shipping container of all packages containing biological materials (See Figure 1 of Appendix 5). Diagnostic specimens and biological products require no hazard warning labels. However, all packages containing etiologic agents must have the label for Etiologic Agents/Biomedical Material affixed to the outer shipping container (See Figure 3 of Appendix 5).

#### **F. Additional Information:**

For further information on this manual chapter, contact the QPSO, DS on 496-2346.

#### **G. Records Retention and Disposal:**

For this chapter, records pertaining to NIH Permits For Import or Export of Biological Materials are retained and disposed of under the authority of NIH Manual [1743](#) "Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedule," Item 1300-B.

**Please see paper copy for Appendices.**

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